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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,234	01/29/2001	Paul G. Loubser	2001-01442	9679

7590

10/21/2003

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EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 10/21/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/772,234

Applicant(s)

LOUBSER, PAUL G.

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/15/03 has been entered.

Response to Amendment/Arguments

2. The declaration under 37 CFR 1.132 filed 9/10/03 is insufficient to overcome the rejection of claims 1-11 based upon the rejections as set forth in the last Office action because: the facts presented are not germane to the rejection at issue. The Examiner has pointed out in the Response to the Amendment section and the Rejection section how the device of Osborne reads on the claims as recited.

3. Applicant's arguments filed 9/10/03 have been fully considered but they are not persuasive.

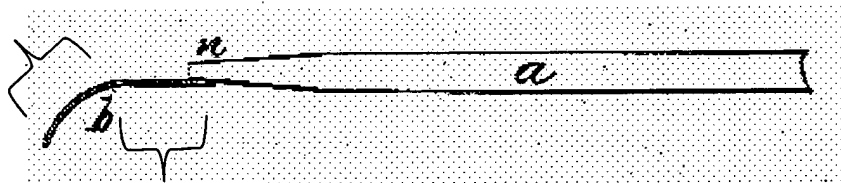
4. In response to applicant's argument that the instant invention lifts the epiglottis upward so that the apparatus may be situated in the vallecula and is designed to be used for an area considerably rostral to the laryngeal outlet, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed

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invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

5. In response to Applicant's arguments that the present invention is solid with a solid enclosed handle, it should be noted that only the offset member is recited as being solid not the handle member in which case the offset member of Osborne is taught as being solid. Furthermore, it should be noted that the handle of Osborne is taught being made of metal, hard rubber, celluloid, all of which can be of a solid material.

6. In response to Applicant's arguments that the proximal member and distal member of Osborne are not of the same length please see the attached drawing Figure 2 below which show the two brackets as being the same length.



7. In response to Applicant's arguments that the Osborne device is oval in contrast to the instant retractor apparatus, it should be noted that the instant retractor apparatus is oval in shape as well. Furthermore, the device of Osborne also has a flat region or portion.

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8. In response to applicant's argument that there is no suggestion to modify the Osborne reference to arrive at a handle member and arcuate offset member that are interconnected, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation is found in the knowledge generally available to one of ordinary skill in the art, i.e., it is known in the art to provide a device that is detachable. Although, Applicant's motivation for making the instant retractor interconnected is different from that stated by the Examiner, the Examiner has nonetheless provided sufficient motivation that would be well within the scope of one of ordinary skill in the art.

9. In response to applicant's argument that there is no suggestion to modify the Osborne reference to arrive at an arcuate offset member that includes a marker, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation is found in the knowledge generally available to one of ordinary skill in the art, i.e., it is known in the art

to provide a marker or indication means for the purpose of providing a guiding means to the practitioner. Although, the instant retractor's function for the marker is different from that stated by the Examiner, the Examiner has nonetheless provided sufficient motivation that would be well within the scope of one of ordinary skill in the art.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-2, 8, 9, 10, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Osborne (US 412409).

12. **As to claim 1**, Osborne teaches a superglottic and peri-laryngeal apparatus for insertion of a supraglottic airway by a medical practitioner into the patient's upper airway, the apparatus comprising an enclosed handle member **a**; a solid arcuate offset member including a straight proximal member configured to be attached to the handle member, a distal member having a contiguous flat compressor-level shield member **b**, an arcuate member disposed medially and contiguously of the proximal member and the arcuate member disposed medially of the handle member and a flat compressor-lever shield member; the distal member of the arcuate offset member configured to be at least as long as the proximal member thereof; the compressor-lever shield member configured to continuously widen from the arcuate offset member to a substantially

broad tip means disposed at the shield member's leading, distal edge, and adapted to match size and configuration of the anatomical feature's of the patient's upper airway; and the arcuate offset member configured to enable the shield member to reach the supraglottic region proximal to the base of the tongue and the vallecula so as to provide sufficient leverage to enable the medical practitioner to compress and lift the tongue and to simultaneously lift the epiglottis in the pharyngeal cavity, while simultaneously flattening the tongue in the laryngeal cavity, for creating sufficient space both in the laryngeal cavity and the pharyngeal cavity to enable the medical practitioner to rapidly insert the supraglottic airway while minimizing tissue trauma and post-procedural patient discomfort.

13. **As to claim 2**, Osborne teaches an apparatus wherein the handle member, the proximal member, arcuate member, and the distal member are integrally constructed.

14. **As to claim 8**, Osborne teaches an apparatus wherein the compression-lever shield member comprises a substantially flat configuration.

15. **As to claim 9**, Osborne teaches an apparatus wherein the compression-lever shield member comprises a concave configuration.

16. **As to claim 10**, Osborne teaches an apparatus wherein the compression-lever shield member comprises a perimeter buffered edge to prevent tissue trauma as the shield member is advanced by the medical practitioner through the patient's pharyngeal cavity into the vallecula.

17. **As to claim 12**, Osborne teaches an apparatus wherein the distal member of the arcuate offset member is configured to be the same length as the proximal member thereof.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 3-7, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne.

20. **As to claims 3-7**, Osborne teaches essentially all of the limitations except for the how the handle member and solid arcuate offset member are interconnected and how the arcuate offset member and the compression-lever shield member are connected and what specifically are the means of connection. However, it would be obvious to one of ordinary skill in the art to modify the apparatus of Osborne so that the various components of the apparatus are interconnected to each other so that they can be detachable for the purposes of replacing parts or for the purposes of ease of cleaning. Furthermore, the means of connection would also be well within the scope of one of ordinary skill in the art of connectors.

21. **As to claim 11**, Osborne teaches essentially all of the limitations except for wherein the arcuate offset member includes a marker means disposed on its proximal

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to the handle member for guiding the medical practitioner when the compressor -lever has been fully inserted into the patient's upper airway. However, it is known in the art to provide a marker means disposed at an end proximal to the handle member for guiding the medical practitioner (See US 6053166).

22.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Aaron J. Lewis
Primary Examiner

mbp